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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/722,357

11/24/2003

Michela Gallagher

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EXAMINER

PURDY, KYLE A

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

10/26/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/722,357	<b>Applicant(s)</b> GALLAGHER ET AL.	
	<b>Examiner</b> Kyle Purdy	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 8/9/2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 44 and 53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

1. The Examiner acknowledges receipt of the amendments filed on 8/9/2010 wherein claim 1 has been amended.
2. Claims 44 and 53 are presented for examination on the merits. The following rejections are made.

### ***Response to Applicants' Arguments***

3. Applicants arguments filed 8/9/2010 regarding the rejection of claims 44 and 53 made by the Examiner under 35 USC 103(a) over Haas et al. (Annals of Clinical Psychiatry, 1997) in view of Petersen et al. (Neurology, 2001) have been fully considered and they are found persuasive. The rejection has been overcome by amendment to the claims.

### **New Rejections, Necessitated by Amendment** ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**6. Claims 44 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haas et al. (Annals of Clinical Psychiatry, 1997, 9(3), 145-147) in view of Petersen et al. (Neurology, 2001, 56, 1133-1142) and Jha et al. Indian J. Pharmacology, 1992, 24, 219-222).**

7. Haas is directed to a treatment for demented elderly aggressive patients with divalproex. Divalproex is a 1:1 mixture of sodium valproate (sodium 2-propylpentanoate, i.e. Applicants elected species) and valproic acid (Applicants elected species in nonionic form). It's taught that divalproex had utility in the 'treatment of behavioral dyscontrol in cognitively impaired individuals.' (see page 146, right column). Moreover, it's taught that divalproex should be considered as a pharmacotherapy for aggressivity in 'cognitively impaired, elderly people' (see abstract).

8. Haas fails to teach treating cognitive impairment associated with Mild Cognitive Impairment (MCI).

9. Petersen teaches that dementia is often preceded by MCI. It's taught that MCI refers to the clinical state of an individual who has impaired memory but is otherwise functions well and does not meet the clinical criteria for dementia.

10. Jha is directed to the effect of valproate on cognitive function in epileptics. Jha teaches that valproate improves intellect, alertness, attention, cooperation and better school performance in epileptic children (see page 222, left column). Table 2 characterizes the effect of valproate on cognitive function where most patients experienced improvement in attention, immediate recall

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and the Bender Gestalt test. Overall, patients showed an improvement in cognitive function (see page 221, right column).

11. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Haas, Petersen and Jha with a reasonable expectation for success in arriving at a method of treating cognitive impairment associated with MCI by administering a composition comprising valproate. While Haas does not teach treating cognitive impairment associated with MCI directly, any ordinary person would have been capable of arriving at such a treatment, see:

Dementia → MCI;

Val → treats Dementia; therefore

Val → treats MCI.

With respect to the treatment of cognitive impairment associated with MCI, this would be the result of valproate administration. Jha teaches that valproate administration to epileptic individuals greatly improved their cognitive abilities such as enhancing their attention, ability to recall information and visuo spatial functions. While Jha is not directed to treating MCI and its symptoms, one would still have reasonable expectation that valproate given to a subject with MCI (i.e. Haas in view of Peterson) would experience improved cognitive function like that observed by Jha. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/  
Examiner, Art Unit 1611  
October 20, 2010*

*/Sharmila Gollamudi Landau/  
Supervisory Patent Examiner, Art Unit 1611*